08/825,992 PAC

PATENT
Atty. Docket No.: 9009.0008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No. 5,776,944)
)
Issued: July 7, 1998)
)
To: Chang Y. Hong, Young K. Kim, Se H. Kim,)
Jay H. Chang, Hoon Choi, Do H. Nam,)
Ae R. Kim, Jin H. Lee, Ki S. Park)
)
Assignee: LG Life Sciences, Ltd.)

For: 7-(4-AMINOMETHYL-3-METHYLOXYIMINOPYRROPLIDIN-1-YL)-1-CYCLOPROPYL-6-FLUORO-4-OXO-1,4-DIHYDRO-1,8-NAPHTHYRIDINE-3-CARBOXYLIC ACID AND THE PROCESS FOR THE PREPARATION THEREOF

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

NOTICE CONCERNING REEXAMINATION OF PATENT SUBJECT TO APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

On May 29, 2003, Applicant, LG Life Sciences, Ltd., Assignee of the entire interest in and to United States Patent No. 5,776,944 ("the '944 patent") granted to Chang Y. Hong, Young K. Kim, Se H. Kim, Jay H. Chang, Hoon Choi, Do H. Nam, Ae R. Kin, Jin H. Lee, and Ki S. Park on the 7th day of July, 1998, for 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid and the process for the preparation thereof, filed an application for patent term extension under 35 U.S.C. § 156. As part of the information required under 37 C.F.R. § 1.740, Applicant informed the Office that :

No reexamination certificate or certificate of correction has been issued on this patent. LG Life Sciences, Ltd. filed a request for reexamination of U.S. Patent No. 5,776,944 on December 27, 2002, which was granted by the U.S. Patent and Trademark Office by an Order mailed February 20, 2003. The reexamination control number is 90/006,498.

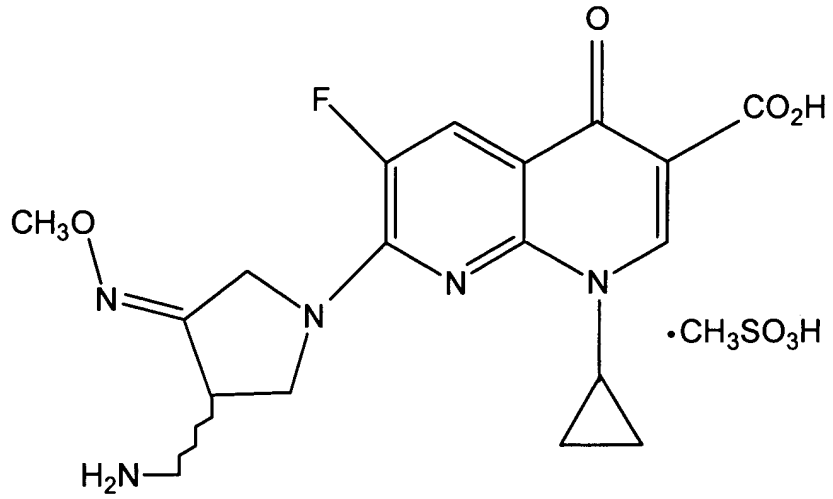
Applicant is submitting this paper to note in the record of this patent term extension application that the reexamination of the '944 patent has concluded and the Office issued an ex parte reexamination certificate on June 14, 2005. A copy of that reexamination certificate is attached. As in the case of the original '944 patent claims, the reexamined claims read on the approved product.

The approved product, FACTIVE® tablets, is a broad spectrum antibacterial agent for oral administration containing gemifloxacin mesylate as the active ingredient. Gemifloxacin is available as the mesylate salt in the sesquihydrate form. Identification of gemifloxacin is as follows:

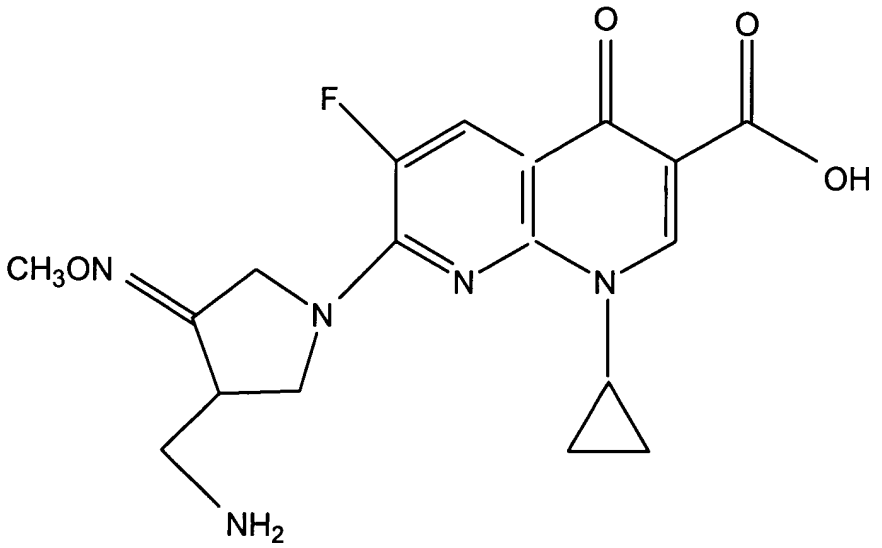
Chemical Name(s): (*R,S*)-7-[(4Z)-3-(aminomethyl)-4-(methoxyimino}-1-pyrrolidinyl]-1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-1,8-naphthyridine-3-carboxylic acid

Empirical Formula of gemifloxacin mesylate: $C_{18}H_{20}FN_5O_4 \bullet CH_4O_3S$

Structural Formula of gemifloxacin mesylate:



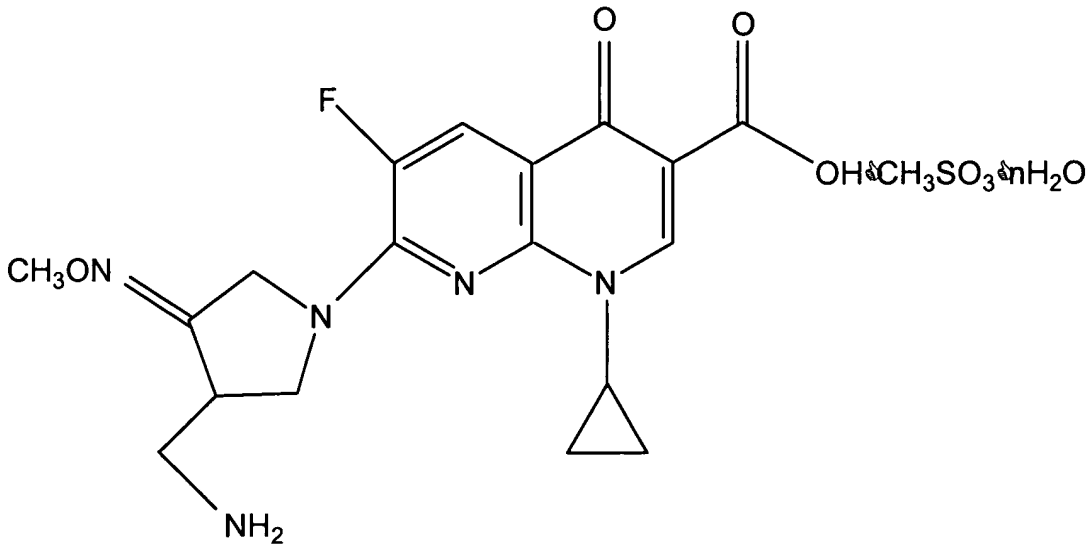
Claims 1-3, 5-7, and 17 claim the active ingredient in FACTIVE® tablets. Claim 1, for example, reads as follows: "7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid represented by the following formula:



or a pharmaceutically acceptable non-toxic salt, physiologically hydrolyzable ester, or isomer thereof." Claim 1 reads on the active ingredient in FACTIVE® tablets.

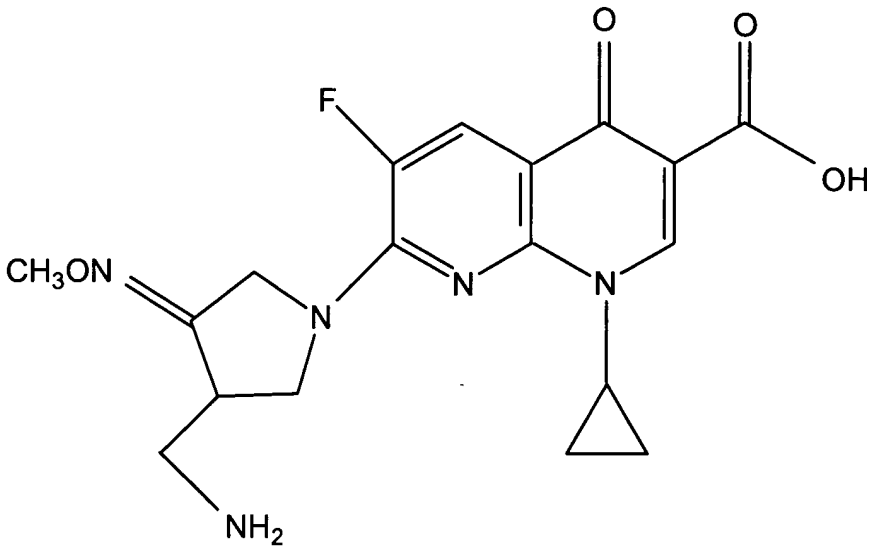
Claim 3 reads as follows: "A hydrate of 7-(4-aminomethyl-3-

methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid methanesulfonate represented by the following formula:

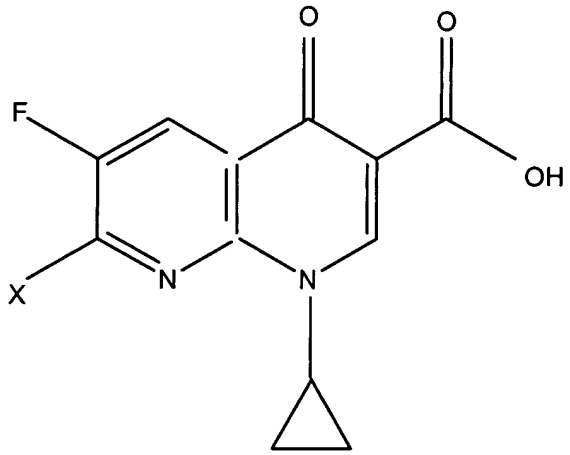


in which n denotes 1, 1.5, 2, 2.5, 3, 3.5 or 4; or an isomer thereof." Claim 3 reads on the sesquihydrate form of the active ingredient of FACTIVE® tablets when n is 1.5. Claim 6, which recites "[t]he hydrate according to claim 3, wherein n is 1.5" is directed to the specific embodiment present in the approved product.

Claims 25-34 claim a process for preparing the active ingredient in FACTIVE® tablets. Claim 25, for example, recites: "A process for preparing a hydrate of a methanesulfonate of 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid represented by the following formula:

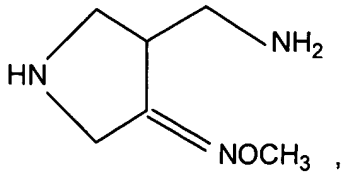


which comprises reacting a quinolone compound represented by the following formula,



in which X represents a halogen, with a pyrrolidine oxime compound represented by the following formula, or a salt thereof,

in a solvent in the presence of an acid acceptor;



reacting the 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid with methanesulfonic acid, wherein a methanesulfonate of the 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid forms; and reacting the methanesulfonate of the 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid with water. Claim 25 reads on a process for preparing the active ingredient in FACTIVE® tablets.

Claims 13-16, 18, and 19 claim an antibacterial composition comprising the active ingredient in FACTIVE® tablets. Claim 15, for example, is directed to an antibacterial composition Claim 15 recites "[a]n antibacterial composition comprising as an active component the hydrate defined in claim 3, together with a pharmaceutically acceptable carrier." Claim 15 reads on the approved product FACTIVE® tablets because the product contains a compound of claim 3 as explained above and a pharmaceutically acceptable carrier (inactive ingredients such as hydroxypropyl methylcellulose).

As is evident from these examples, the reexamined claims of the '944 patent read on the approved product. Accordingly, although the originally issued claims were amended during reexamination, the '944 patent remains eligible for patent term extension under Section 156.

When the patent term extension application for the '944 patent was filed, Applicant also filed patent term extension applications for U.S. Patent Numbers

5,633,262 and 5,962,468 based on the same approved product. Concurrently with this Notice, Applicant is expressly abandoning the patent term extension applications for those two patents in favor of the application for the '944 patent. Accordingly, Applicant respectfully requests that the Office timely issue a Certificate Extending Patent Term Under 35 U.S.C. § 156.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: Charles E Van Horn
Charles E. Van Horn
Reg. No. 40,266

Date: August 24, 2005

Attachments: Ex Parte Reexamination Certificate US 5,776,944 C1,
issued June 14, 2005